

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
13 February 2003 (13.02.2003)

PCT

(10) International Publication Number  
**WO 03/011378 A1**

(51) International Patent Classification<sup>7</sup>: A61M 5/20,  
5/32, 5/50

Jeremy [GB/GB]; 16 Cranham Street, Jericho, Oxford  
OX2 6DD (GB). HANSEN, Nick [GB/GB]; 13 Danes-  
moor, Banbury, Oxford OX16 1PZ (GB).

(21) International Application Number: PCT/GB02/03428

(22) International Filing Date: 26 July 2002 (26.07.2002)

(74) Agents: JAMES, Michael, John, Gwynne et al.;  
Wynne-Jones, Laine & James, 22 Rodney Road, Chel-  
tenham, Gloucestershire GL50 1JJ (GB).

(25) Filing Language: English

(81) Designated States (*national*): JP, US.

(26) Publication Language: English

(30) Priority Data:  
0118419.1 28 July 2001 (28.07.2001) GB

(84) Designated States (*regional*): European patent (AT, BE,  
BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT,  
LU, MC, NL, PT, SE, SK, TR).

(71) Applicant (*for all designated States except US*): OWEN  
MUMFORD LIMITED [GB/GB]; Brook Hill, Wood-  
stock, Oxon OX20 1TU (GB).

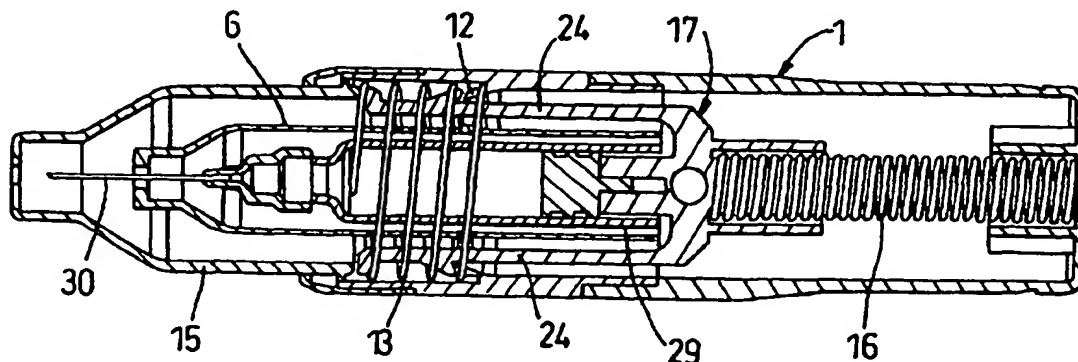
Published:  
— with international search report

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): MARSHALL,

*For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.*

(54) Title: IMPROVEMENTS RELATING TO INJECTION DEVICES



(57) Abstract: An injection device for a syringe incorporates a housing (1) for a syringe (29). A needle shroud (15) is captive to the leading end of the housing and is movable before use between extended and retracted positions. A drive member (17) is releasable from a rearward position within the housing to urge the syringe forwards to project its needle (30) beyond the retracted needle shroud (15) and then to express a dose through the needle. Locating members (12) on the housing capture the drive member (17) at its forward position (attained after expressing the dose). The captured drive member (17) is also arranged to block retraction of the needle shroud (15) from its extended position.

WO 03/011378 A1

Improvements relating to Injection Devices

This invention relates to injection devices. It is concerned with those where a syringe is enclosed in a housing of barrel-like form, the syringe being propelled forward by a drive mechanism to project its needle, followed by continued operation of the drive mechanism to push the plunger of the syringe and eject a dose. This will leave the needle sticking out, unless certain measures are taken. One answer is to have an arrangement for withdrawing the syringe back into the housing, while another is to have a needle shroud that moves out from the housing to enclose the needle. Of course, this must not interfere with the actual injection operation. It has therefore been proposed that the shroud is normally spring-urged forwardly to a needle protecting position, but when the device is pushed against the patient's skin the shroud is forced to retract against its spring. After injection, the spring pushes the shroud forwards again.

It is desirable for there to be an arrangement for automatically locking the shroud at its fully projecting position after the injection but not before, and it is the aim of this invention to provide a way of achieving this.

According to the present invention there is provided an injection device for a syringe, the device comprising a

housing for the syringe, a needle shroud captive to the leading end of the housing and movable before use between extended and retracted positions, a drive member releasable from a rearward position within the housing to urge the syringe forwards to project its needle beyond the retracted needle shroud and then to express a dose through the needle, and locating members on the housing for capturing the drive member at its forward position attained after expressing the dose, and wherein the captured drive member is arranged to block retraction of the needle shroud from its extended position.

The needle shroud will normally be biased forwardly so that, in use, as the device is pressed against the skin, the shroud is pushed back into the housing. The user will then release the drive member.

That drive member will generally be spring-actuated, and in the preferred form it will have a plunger that enters the rear end of the syringe to engage the piston within the syringe, thereby supporting the syringe at its rear end. The needle of the syringe will ideally have a collapsible rubber sheath, which acts as a support for the forward end of the syringe. The tip of the sheath may be located in a small cup-like formation of the housing with a central aperture through which the needle, but not the

sheath, can penetrate. As the syringe is driven forwards, the needle pierces the sheath to project through and beyond the cup-like formation while the sheath "concertinas" into a shorter length, helping to arrest the syringe when it is fully compressed.

The drive member may have arms that extend forwardly to co-operate with the interior of the housing and the needle shroud. As the drive member moves forwards, these arms can be flexed inwards by locating formations on the housing to cause their leading ends to enter the retracted needle shroud. After the injection, as the needle shroud is released and moves forwards, it passes beyond the arms, which disengage and flex back outwards. Abutments on the outsides of the arms can then be provided to be in registry with abutments on the inside of the housing, after completion of the injection operation, so that the drive member cannot be pushed back. Preferably these abutments will be hooked for positive interengagement. At the same time, after completion of the injection operation, the ends of the arms are ideally aligned with the needle shroud, and provide abutments to prevent the shroud being pushed back.

For a better understanding of the invention, one embodiment will now be described, by way of example, with reference to the accompanying drawings, in which:

Figures 1 to 6 are axial sections of an injection device in various stages from pre-use to post-use,

Figure 7 is an enlarged detail of Figure 6, and

Figures 8 and 9 are perspective views of a drive member of the device.

The injection device has a composite barrel 1 with a rear portion 2 having a closed rear end 3, an intermediate portion 4, and a forward portion 5. The intermediate portion 4 carries a co-axial inner tube 6 by radial spokes 7 immediately to the rear of a forward facing inner shoulder 8. The leading end 9 of the tube 6 constricts and has a small aperture 10 formed by an inward annular flange 11 at its extremity. Two diametrically opposed lugs 12 project inwardly and forwardly from the shoulder 8, which locates the rear end of a helical spring 13. Cradle-like or U-shaped guides 14 as best seen in Figure 7 are formed on the outside of the tube 6 directly opposite these lugs 12. At its forward end the spring 13 bears against a needle shroud 15 made captive to the barrel by the forward portion 5 but capable of sliding backwards, telescoping further into the barrel to compress the spring 13 and to nest closely over the leading end 9 of the tube 6.

The rear end 3 internally provides a seat for a drive spring 16 which acts on a drive member 17 as best seen in

Figures 8 and 9. It has a hollow cylindrical portion 18 to receive the forward end of the spring 16, which also locates around an x-section stem 19 co-axially within the portion 18 and projecting rearwardly beyond it. Forward of this, the cylinder 18 steps inwards to a co-axial intermediate portion 20 solid apart from a transverse bore 21, and then steps further inwards into a co-axial plunger 22 with a central bore 23 open to its leading end. Branching out and then forwardly from the intermediate portion 20 there are two diametrically opposed arms 24 with outwardly projecting lugs 25 at their free ends, and each with a tooth 26 a short distance back from the lug 25. Each tooth 26 slopes at an acute angle outwardly and rearwardly and then slants back in at a less acute angle. On one side the cylinder 18 has a forwardly and outwardly projecting tongue 27 which is part of the trigger mechanism for releasing the drive member 17, and opposite that tongue there is a longitudinal heel 28 which can run in a track (not shown) formed on the inside of the barrel 1 to ensure that the drive member 17 is correctly orientated and runs true.

A conventional syringe 29 is co-axially carried within the tube 6. Its needle 30 has a rubber sheath 31 whose closed forward end locates in the cup-like leading end 9 of

6

the tube 6. The sheath 31 is never removed, but it is shown only in Figures 1 and 4. The plunger 22 of the drive member 17 enters the rear end of the syringe and cooperates with its piston 32, which has a rear central stud 33 that locates in the bore 23. The syringe 29 is thus carried co-axially within the tube 6 by the tip of the sheath 31 and the stud 33: there is no contact between the body of the syringe and the tube 6.

Initially, the device is made safe by a pin (not shown) transversely through the barrel 1 and through the bore 21, locking the drive member 17 in its rearward position with the spring 16 compressed, as in Figure 1. When this pin is removed, the device can be fired. The user first presses the leading end of the needle shroud 15 against the area to be injected and urges the device forwards. The needle shroud 15 is forced back until the spring 13 is fully compressed. The sheathed tip of the needle 30 is still within the device, which has now reached the position of Figure 3.

The trigger is operated, allowing the spring 16 to act, and that drives the member 17 forwards. The effective solidity of the dose within the syringe 29 causes that to be moved forwards to project the needle 30, which pierces the end of the sheath 31, leaving that to concertina into a

short length within the leading end 9 as indicated in Figure 4. It is too bulky to pass through the aperture 10. The needle 30 therefore enters the flesh. During this movement, the lugs 25 and 12 meet. The latter may be deflected slightly outwardly but any such movement will be limited by the compressed spring 13. The arms 24, however, will be flexed inwardly, allowing the lugs 25 to snap past and bear outwardly against the inside of the shroud 15. The arms 24 start to pass through the guides 14 at this time and they help to keep the arms properly aligned. The syringe 29 reaches the limit of its forward movement by the sheath 31 becoming fully compressed, the teeth 26 simultaneously coming up against the rear sloping sides of the lugs 12. This is the position of Figure 4.

Continued forward movement of the member 17 ejects the dose through the needle 30 and causes the teeth 26 and lugs 12 to act as wedges and flex the arms 24 further inwards. The teeth 26 go past the lugs 12 just before the injection is finished, which is when the intermediate portion 20 of the drive member 17 comes up against the rear end of the syringe, as shown in Figure 5. The device is then withdrawn, and this allows the spring 13 to act and push the needle shroud 15 forward again, sliding free of the teeth 26 and then the lugs 25. The arms 24 can then spring



outwards again to their natural positions, and this causes the teeth 26 to hook with the lugs 12 if there is any reverse movement. If the needle shroud 15 is pushed back against the lugs 25 and then twisted, pushing the ends of the arms 24 circumferentially, the guides 14 will resist this and keep the teeth 26 in registry with the lugs 12.

Thus, the drive member 17 is held against retraction, while the needle shroud 15, still trapped by the forward barrel portion 5 against removal, is prevented from rearward movement by abutment with the lugs 25. The needle 30, therefore, although still projecting from the tube 6, is safely inside the shroud 15.

CLAIMS

1. An injection device for a syringe, the device comprising a housing for the syringe, a needle shroud captive to the leading end of the housing and movable before use between extended and retracted positions, a drive member releasable from a rearward position within the housing to urge the syringe forwards to project its needle beyond the retracted needle shroud and then to express a dose through the needle, and locating members on the housing for capturing the drive member at its forward position attained after expressing the dose, and wherein the captured drive member is arranged to block retraction of the needle shroud from its extended position.

2. An injection device according to claim 1, wherein the needle shroud is biased forwardly so that, in use, as the device is pressed against the skin, the shroud is pushed back into the housing.

3. An injection device according to claim 1 or claim 2, wherein the drive member is spring-actuated.

4. An injection device according to claim 3, wherein the drive member has a plunger that enters the rear end of the syringe to engage the piston within the syringe, thereby supporting the syringe at its rear end.

5. An injection device according to any one of claims 1.

to 4, wherein the needle of the syringe has a collapsible rubber sheath which acts as a support for the forward end of the syringe.

7. An injection device according to claim 6, wherein the tip of the sheath is located in a small cup-like formation of the housing provided with a central aperture through which the needle, but not the sheath, can penetrate.

7. An injection device according to any one of claims 1 to 6, wherein the drive member has arms that extend forwardly to co-operate with the interior of the housing and the needle shroud.

8. An injection device according to claim 7, wherein locating formations on the housing are provided to cause the leading ends of the arms to be flexed inwards and to enter the retracted needle shroud.

9. An injection device according to claim 8, wherein abutments on the outsides of the arms are provided to be in registry with said locating formations on the inside of the housing so that, after completion of the injection operation, the drive member cannot be pushed back.

10. An injection device according to claim 9, wherein said abutments are hooked for positive interengagement.

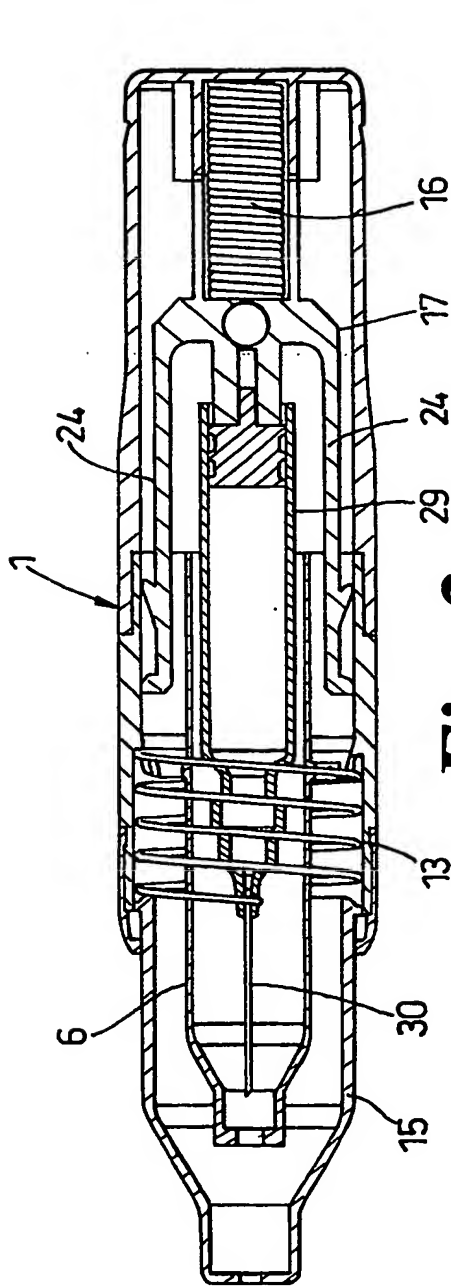
11. An injection device according to any one of claims 7 to 10, wherein the ends of the arms are aligned with the

needle shroud, after completion of the injection operation, and provide abutments to prevent the shroud being pushed back

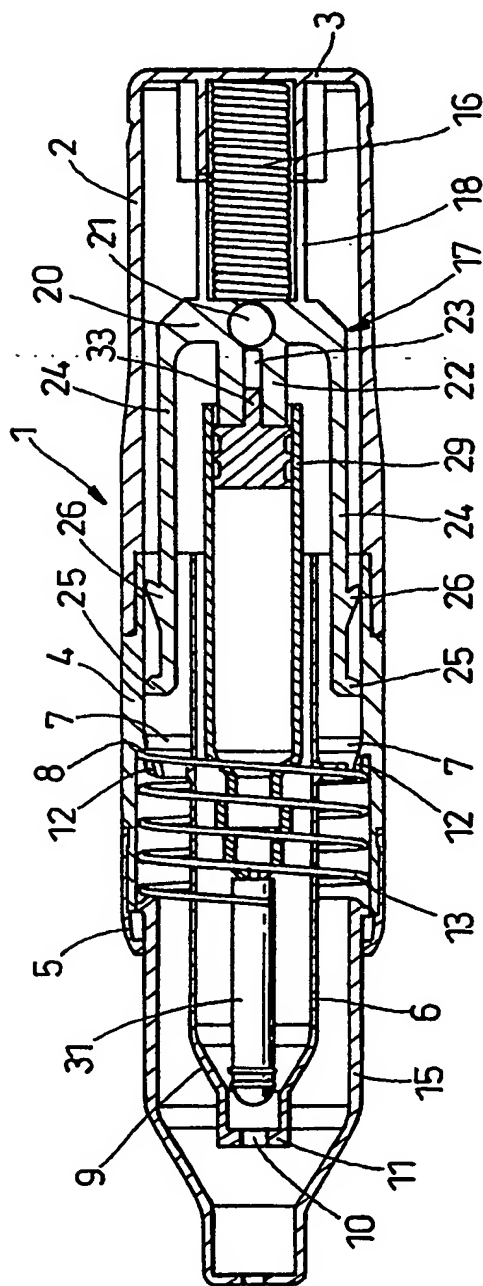
12. An injection device of a form substantially as herein described with reference to the accompanying drawings.

13. Any novel combination of features of an injection device of a form as herein described and/or as illustrated in the accompanying drawings.

1/5

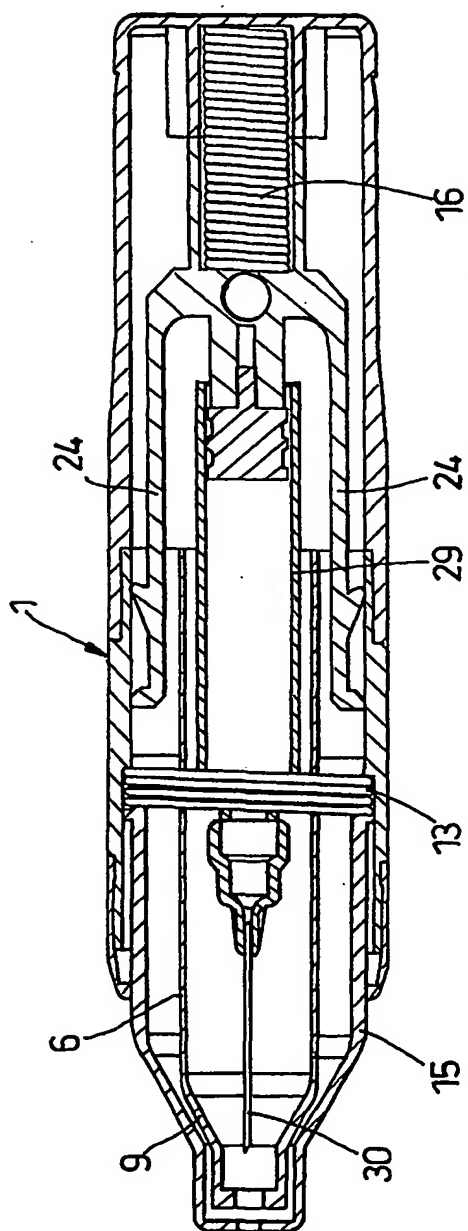


**Fig. 2**

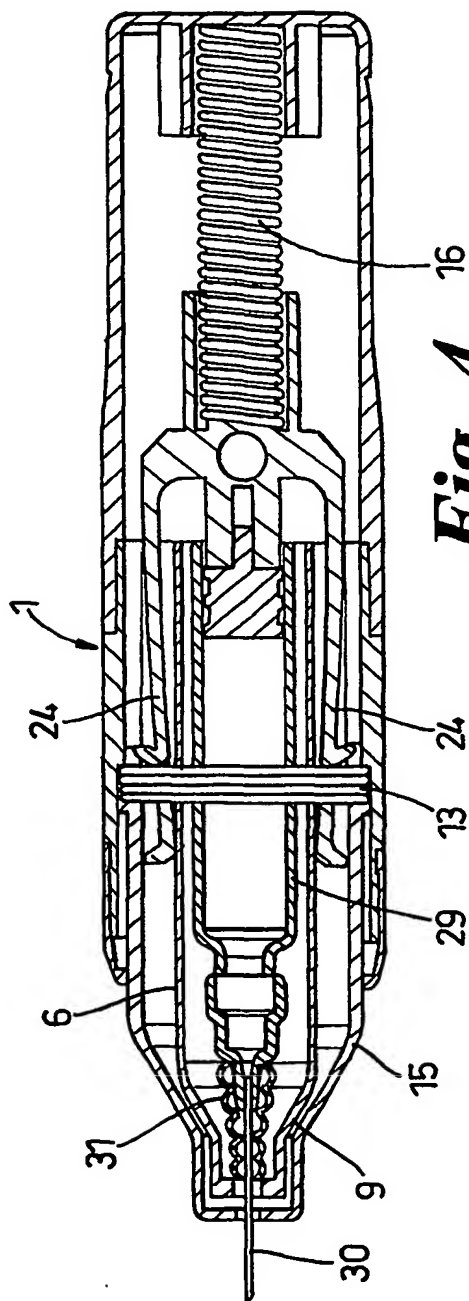


**Fig. 1**

2/5

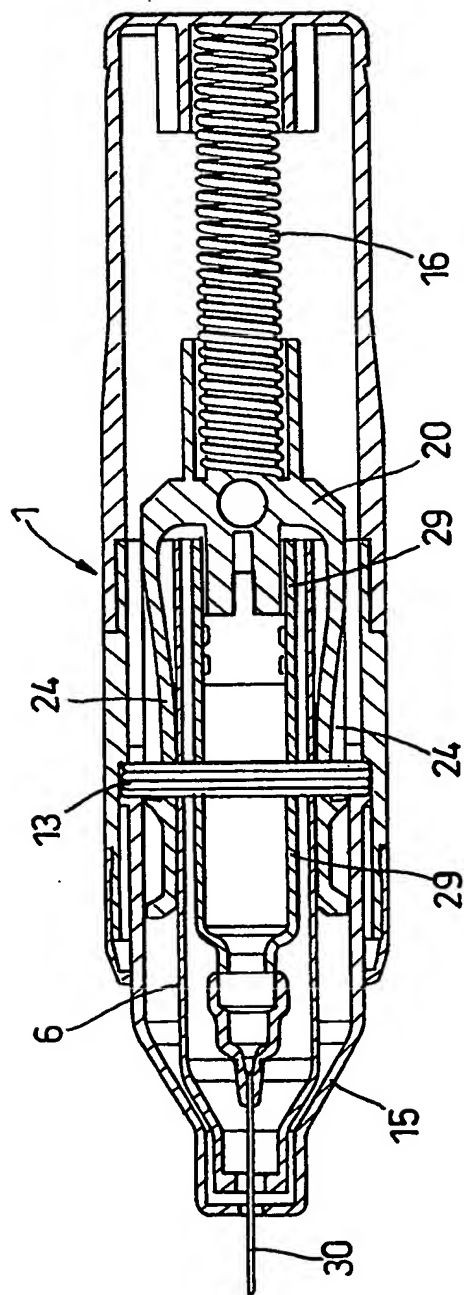


**Fig. 3**

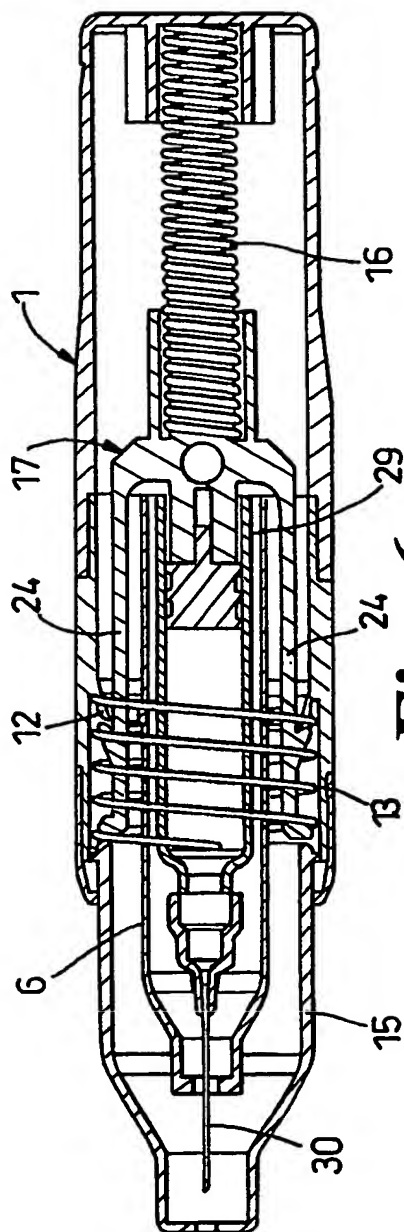


**Fig. 4**

3/5

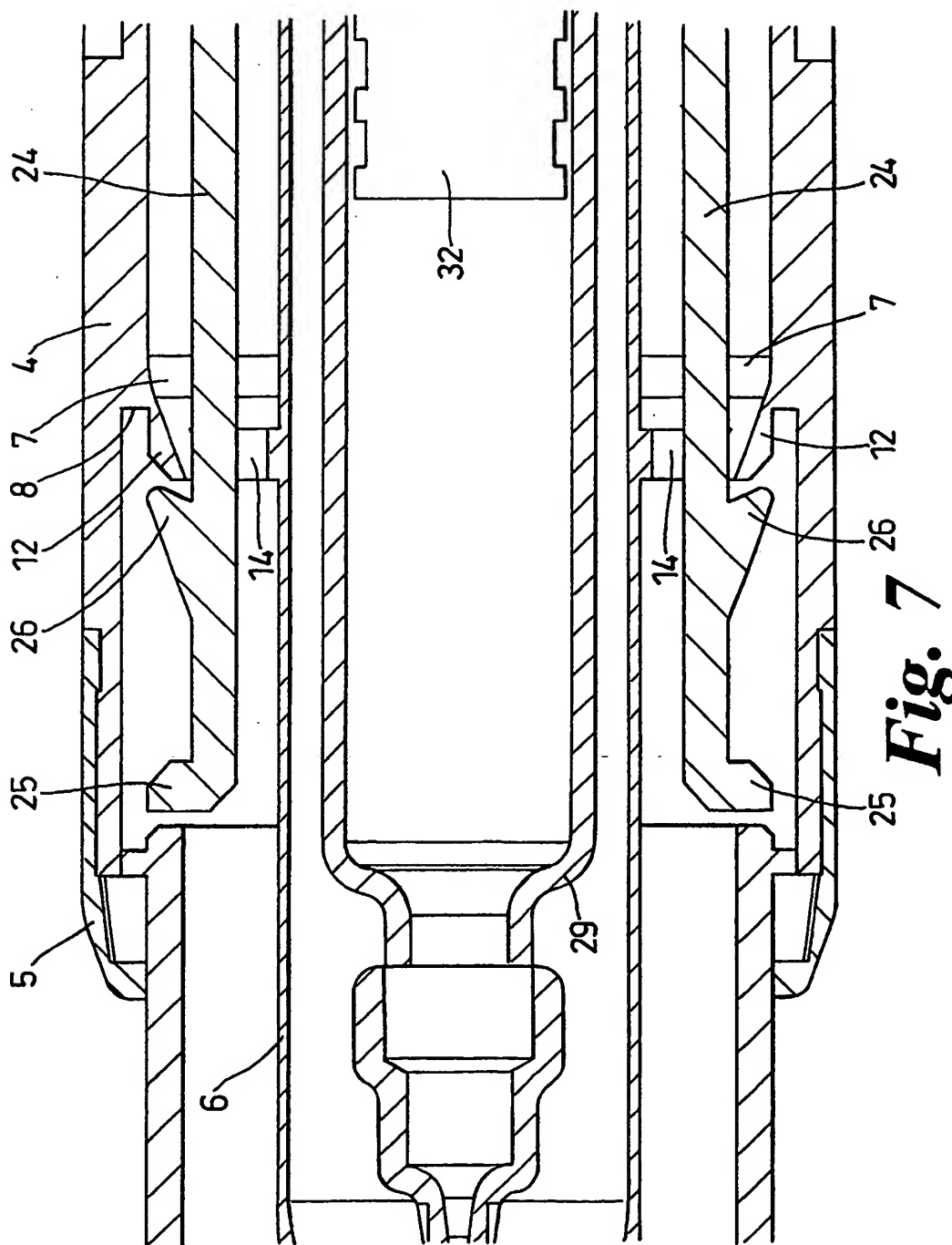


**Fig. 5**



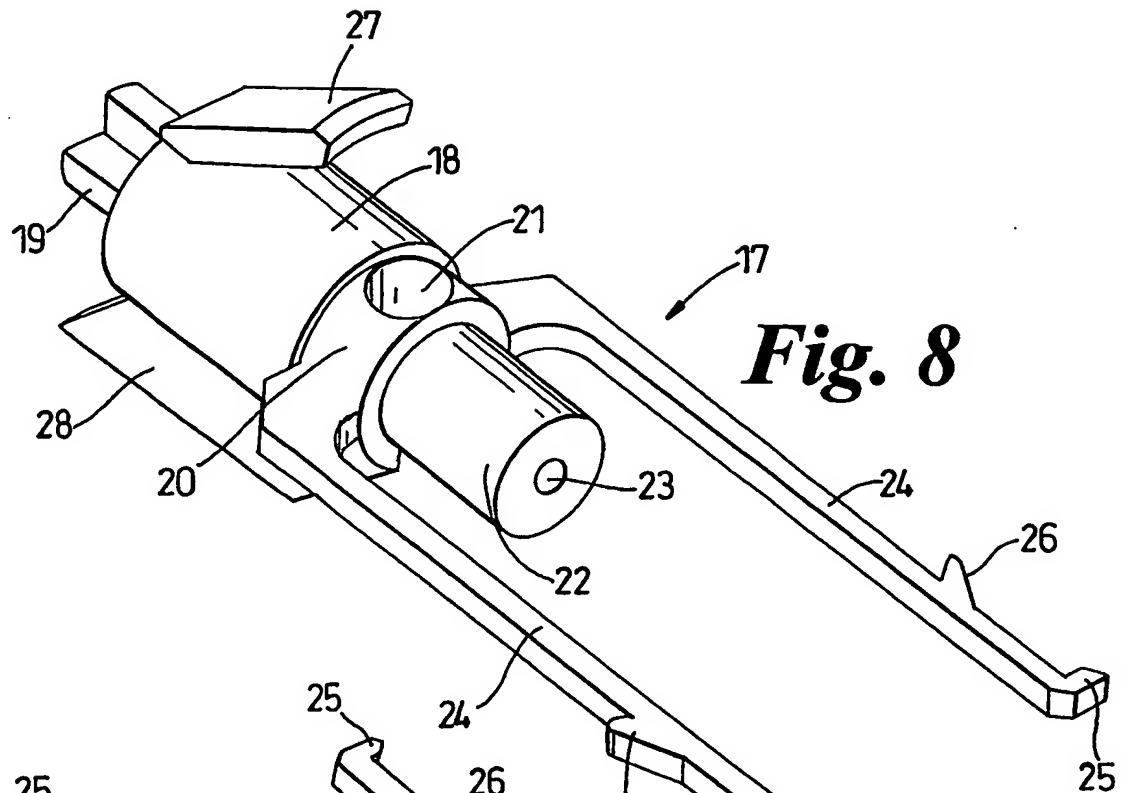
**Fig. 6**

4/5

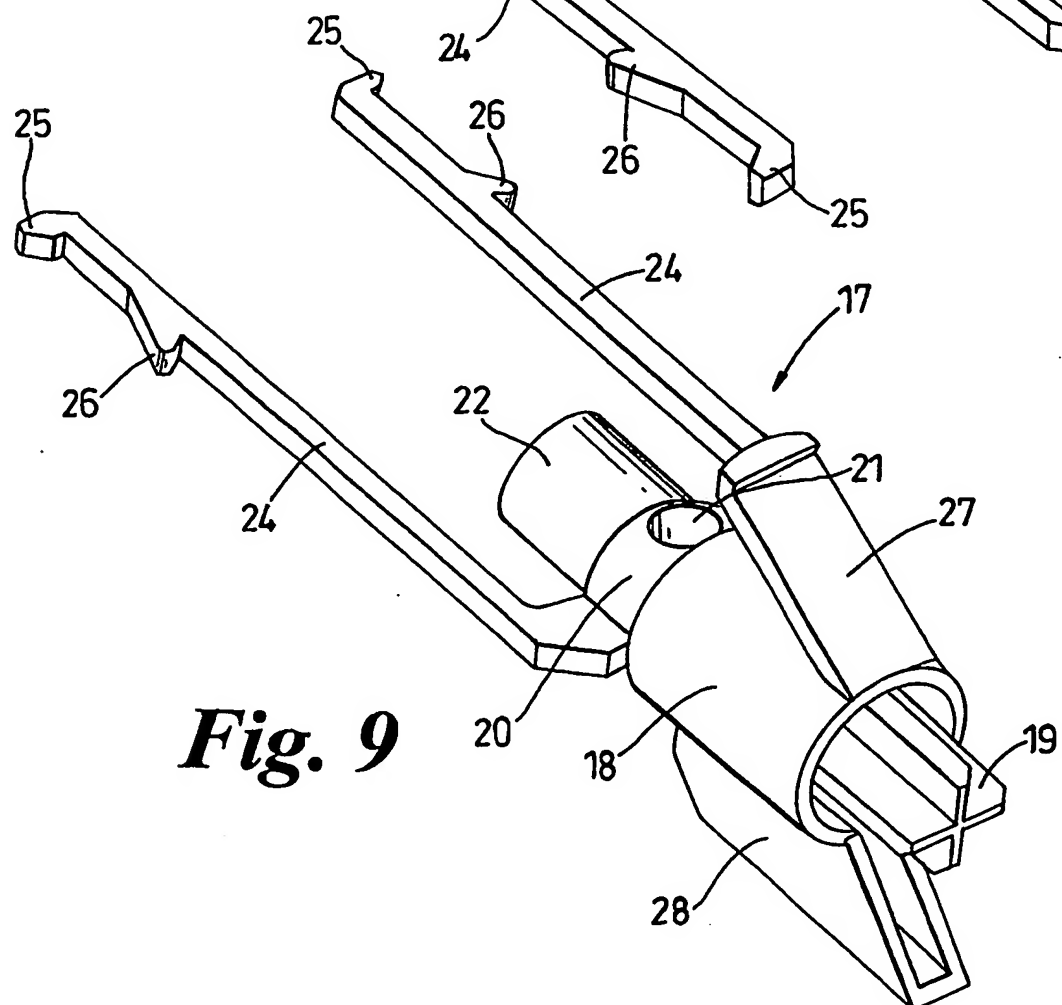




5/5



**Fig. 8**



**Fig. 9**

## INTERNATIONAL SEARCH REPORT

Int l tional Application No

PCT/GB 02/03428

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M5/20 A61M5/32 A61M5/50

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 405 362 A (KRAMER GEORGE C ET AL) 11 April 1995 (1995-04-11) column 6, line 33 -column 8, line 41 figures 8-12	1-11
A	US 5 957 897 A (JEFFREY PETER) 28 September 1999 (1999-09-28) column 5, line 33-54 figures 1-4	6
A	WO 91 11212 A (GILLILAND GERARD PHILIP ; PARSONS JOSEPH REDVERS BULLER (AU)) 8 August 1991 (1991-08-08) page 5, line 1 -page 6, line 10 figures 1A-3D	7-11

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document but published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*&amp;\* document member of the same patent family

Date of the actual completion of the international search

4 November 2002

Date of mailing of the international search report

15/11/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Azaizia, M

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/GB 02/03428

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 12, 13  
because they relate to subject matter not required to be searched by this Authority, namely:  
The claims rely on references to the description and/or the drawings (Rule 6.2(a) PCT).
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 02/03428

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5405362	A	11-04-1995	US 5271744 A	21-12-1993
			US 5176643 A	05-01-1993
			US 5960797 A	05-10-1999
			US 5868711 A	09-02-1999
			US 5451210 A	19-09-1995
			AU 659374 B2	11-05-1995
			AU 1912492 A	21-12-1992
			AU 2843095 A	12-10-1995
			CA 2109106 A1	12-11-1992
			EP 0582651 A1	16-02-1994
			JP 6508773 T	06-10-1994
			WO 9219296 A2	12-11-1992
US 5957897	A	28-09-1999	AU 709098 B2	19-08-1999
			AU 2680995 A	15-01-1996
			CA 2193231 A1	28-12-1995
			EP 0956061 A1	17-11-1999
			WO 9535126 A1	28-12-1995
			JP 10507935 T	04-08-1998
WO 9111212	A	08-08-1991	WO 9111212 A1	08-08-1991